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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,209	11/16/2001	Nigel Dunn-Coleman	GC648-2	6062

5100 7590 08/18/2005

GENENCOR INTERNATIONAL, INC.  
ATTENTION: LEGAL DEPARTMENT  
925 PAGE MILL ROAD  
PALO ALTO, CA 94304

EXAMINER

KALLIS, RUSSELL

ART UNIT PAPER NUMBER

1638

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/991,209		DUNN-COLEMAN ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Russell Kallis		1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-12,14,15,18,19,23,25,27-33,75 and 77-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-12,14,15,18,19,23,25,27-33,75 and 77-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)       |
| Paper No(s)/Mail Date <u>9/09/2002</u> .   | 6) <input checked="" type="checkbox"/> Other: <u>attached seq doc #1 and #2</u> . |

### **DETAILED ACTION**

Claims 3-12, 14-15, 18-19, 23, 25, 27-33, 75 and 77-83 are pending and examined.

Rejection of Claims 1-2, 8, 14 and 23 under 35 U.S.C. 102(a) is withdrawn in view of Applicant's amendments.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112***

Claims 3-12 14-15, 18-19, 23, 25, 27-33 and 77-79 remain and new Claims 80-83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/17/04, 11/03/2004 and 3/09/2005. Applicant's arguments filed 8/16/04, 2/18/2005 and 6/03/2005 have been fully considered but they are not persuasive.

Applicant asserts that their statement that one could isolate ferulic acid esterases and that ferulic acid esterases were known in the art is not inconsistent with the teaching in the specification that only one FAE gene had been cloned (response pages 5-6). Applicant's amendment to Claims 3 and 74 to a FAE1 encoding polynucleotide sequence from *Aspergillus niger* does not fulfill the requirements under 35 USC 112 1<sup>st</sup> paragraph written description, because there is either no teaching of a representative number of FAE1 sequences in the specification or the art; or there is no teaching of conserved sequences required for FAE1 activity

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that would allow for identification of an FAE1 encoding polynucleotide. Further, Applicant's specification points to SEQ ID NO: 1 encoding an FAE1 amino acid sequence of SEQ ID NO: 2 that bears a closer resemblance at the level of sequence identity to FAE III (see de Vries R. *et al.* Applied and Environmental Microbiology, Dec. 1997; Vol. 63, No. 12; pp. 4638-4644 and attached sequence report) than to the amino acid sequence of FAE1, which is encoded by and also known as faeB; see DeVries R. *et al.* (Biochem. J. (2002) Vol. 363, pp. 377-386 and attached GenBank Accession GI: 23821545) who teach isolation of FaeB a second feruloyl esterase from *Aspergillus niger* that encodes FAE1 (see page 377 column 1 line 13 to column 2 line 21 and the Discussion section on page 384 in column 1 the 1<sup>st</sup> paragraph and on page 385 in column 2 lines 2-4). FAE-III is 281 amino acids in length and FAE1 is 521 amino acids in length; and Applicant's polypeptide sequence of SEQ ID NO: 2 is 281 amino acids in length. Clearly, Applicant has not clarified the description of polynucleotides encoding an FAE1 amino acid sequence. Although each and every embodiment need not be described, from Applicant's lack of written description of the claimed genus it remains unclear what features identify a ferulic acid esterase or an FAE1 encoding polynucleotide.

Claims 3-12 14-15, 18-19, 23, 25, 27-33 and 77-83 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transgenic Festuca, Lolium, Sorghum, Zea, Triticum, Avena and Poa comprising a polynucleotide encoding an ferulic acid esterase enzyme from *Aspergillus niger* of SEQ ID NO: 2 wherein expression of the *Aspergillus* ferulic acid esterase is targeted to the vacuole, ER, golgi apparatus or apoplast, does not reasonably provide enablement for any grass plant comprising an FAE1 encoding polynucleotide or any ferulic acid esterase encoding polynucleotide sequence other than polynucleotide

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sequence encoding the amino acid of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/17/04, 11/03/2004 and 3/09/2005. Applicant's arguments filed 8/16/04, 2/18/2005 and 6/03/2005 have been fully considered but they are not persuasive.

Applicant asserts that their statement that one could isolate ferulic acid esterases and that ferulic acid esterases were known in the art is not inconsistent with the teaching in the specification that only one FAE gene had been cloned (response pages 5-6). Applicant's amendment to Claims 3 and 74 to a FAE1 encoding polynucleotide sequence from *Aspergillus niger* does not fulfill the requirements under 35 USC 112 1<sup>st</sup> paragraph enablement because the specification does not teach how to distinguish an FAE1 from an FAE-III enzyme, the state of the art did not recognize at the time of the effective filing date common identifying features for an FAE1 polypeptide, Applicant has not provided working examples of FAE1 enzymes sufficient reduce the amount of undue trial and error experimentation that would be required to isolate a polynucleotide encoding an FAE1 enzyme, and hence reduce the unpredictability in the art. Further, see arguments and art presented under written description.

Given the unpredictability in the art as to which ferulic acid esterase encoding polynucleotides would have activity upon a conjugated ferulic acid substrate; the breadth of the claims encompassing a non-exemplified ferulic acid esterase 1 encoding polynucleotide; the lack of guidance in the examples of the specification or in the prior art; undue trial and error experimentation would be needed by one skilled in the art to make and clone a multitude of non-

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exemplified ferulic acid esterase 1 encoding polynucleotides and would require one of skill in the art to test in a myriad of non-exemplified grass plants for an altered phenotype in a multitude of non-exemplified transformed plant grass species. Therefore, the invention is not enabled for the scope set forth in the claims.

***Claim Rejections - 35 USC § 103***

Claims 3-12 14-15, 18-19, 23, 25, 27-33 and 77-79 remain and new Claims 80-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson *et al.* U.S. Patent 6,143,543 issued November 7, 2000 in view of Bartolome B. *et al.*, Applied and Environmental Microbiology; January 1997, pages 208-212. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/17/04, 11/03/2004 and 3/09/2005. Applicant's arguments filed 8/16/04, 2/18/2005 and 6/03/2005 have been fully considered but they are not persuasive.

The claims are broadly drawn to plants comprising an isolated FAE1 encoding polynucleotide, wherein the specification circuitously defines an FAE1 encoding polynucleotide as any nucleic acid sequence comprising the coding region of an FAE1 gene or which encodes an FAE1 polypeptide, or that hybridizes under low stringency to a probe of anywhere from 8 to 300 nucleotide of the sequence disclosed in WO 98/14594 also U.S. Patent 6,368,833 that teaches the FAE-III encoding polypeptide from *Aspergillus niger*.

Michelson teaches a polynucleotide encoding a ferulic acid esterase (FAE III) from *Aspergillus niger* in columns 8-9 and methods of plant transformation in columns 16-17 and 21-22, wherein a plant comprising an expression cassette comprising a ferulic acid esterase encoding polynucleotide in plants derived from *Aspergillus niger*, operably linked to a promoter,

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is taught as an embodiment of the invention and wherein the the release of ferulic acid and diferulate dimers from grass cell walls (columns 27-28) inherently teaches the sequence of the targeting sequence from *Aspergillus niger* ferulic acid esterase (see the first non-patent publication listed in references cited, de Vries *et al.*, on page 4640 column 2 and also page 16 of specification); and further teaches the advantages of using the FAE enzyme to alter cell walls of wheat (column 1 lines 1-65), that cereal plants are preferred plants for transformation (column 10 lines 8-9), and the addition of a second gene of interest such as a gene encoding a xylanase may give additional nutritional value to a food or feed or crop (lines 4-24, 50-51 and in column 13 lines 4-7).

Michelson does not teach a polynucleotide encoding a xylanase.

Bartolome teaches recombinant expression cassettes comprising XylD and XylA (page 208, column 2 in Materials and Methods) and that a xylanase in combination with a ferulic acid esterase from *Aspergillus niger*, together more effectively released ferulic acid from the cell walls of barley and wheat cell walls than either enzyme alone (see page 208, columns 1 and 2).

It would have been obvious at the time of Applicant's invention to modify the invention of Michelson to include an expression cassette comprising a polynucleotide sequence encoding a xylanase, operably linked to a promoter. One of skill in the art would have been motivated by the teachings of Michelson of the genetic engineering of cereal crop plants to express a ferulic acid esterase encoding polynucleotide and motivated by the success of Bartolome in enhancing the release of ferulic acid from cell walls of wheat and barley by a ferulic acid esterase in concert with a xylanase made from recombinant expression cassettes, and that one would have had a reasonable expectation of success of expressing the ferulic acid esterase and xylanase encoding

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genes in transformed plants; wherein using either an inducible, senescence, heat shock, or constitutive promoter, a KDEL ER retention sequence, and a stop codon are obvious optimizations of design parameters and by Applicant's own teachings in the specification that inducible, senescence, heat shock, and constitutive promoters, the KDEL ER retention sequence, and termination sequences as well as methods of transforming and regenerating transformed plants are well known in the art (see specification pages 19-23).

Applicant asserts that motivation to modify the invention, disclosure of all of the elements of the claimed invention, and a reasonable expectation of success has not been established because the expression cassette as claimed includes a targeting sequence and that stable expression is not taught or suggested (response page 8).

The *Aspergillus* sequence of the '543 Patent, known in the art, inherently teaches a signal sequence; see the first non-patent publication listed in references cited, de Vries *et al.*, on page 4640 column 2. Further, there is no evidence to suggest that the FAE and the techniques taught in the specification of Michelson would not result in the stable expression of FAE in a transformed *Festuca*, *Lolium*, *Sorghum*, *Zea*, *Triticum*, *Avena* or *Poa* plant.

Applicant asserts that there is no teaching of how recombinant expression of an FAE in grass plants should be accomplished (response page 8). Transformation of plants is provided by the '543 reference. Further, the '543 reference provides motivation to transform cereal plants e.g. *Festuca*, *Lolium*, *Sorghum*, *Zea*, *Triticum*, *Avena* and *Poa* as argued supra. Moreover, methods of transforming cereals and grasses were known in the art see Applicant's specification pages 22-23.

All claims are rejected.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.  
July 29, 2005

**RUSSELL P. KALLIS, PH.D.**  
**PATENT EXAMINER**

*Russell Kallis*

attached seg doc #1

	Best Local Similarity	97.9%; Pred. No. 5.3e-113;	Matches 27;	Conservative 3;	Mismatches 3;	Indels 0;	Gaps 0;
Qy	1	MKQFSAXHVLAVVVTAGHALAASQTGISEDLYSRVLVEMATISQAAYADLCNPSTIIKGE	60				
		:					
Db	1	MKQFSAKYAIAVVVTAGHALAASQTGISEDLYTRVLVEMATISQAAYADLCNPSTIIKGE	60				
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Db	61	KIYNSQTDINGWILRRDSSKEIITVFRGTGSDTNLQDNTNYLTPFDTLPCNGCEVHVG	120				
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RESULT 2  
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AC 042815;  
DT 28-FEB-2003 (Rel. 41, Created)  
DT 28-FEB-2003 (Rel. 41, Last sequence update)  
DT 28-FEB-2003 (Rel. 41, Last annotation update)  
DE Feruloyl esterase A precursor (EC 3.1.1.73) (Ferulic acid esterase A).  
GN FAEA.  
OS Aspergillus tubingensis.  
OC Eukaryota; Fungi; Ascomycota; Pezizomycotina; Eurotiomycetes;  
OC Euryales; Trichocomaceae; mitosporic Trichocomaceae; Aspergillus.  
OX NCBI\_TaxID=5068;  
[1]  
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SPRATN=NNW756;  
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RA de Vries R.P., Michelsen B., Poulsen C.H., Kroon P.A.,  
RA van der Wevel R.H.H., Faulds C.B., Williamson G.,  
RA van den Hombergh J.P.T.W., Visser J.;  
RT "The faea genes from Aspergillus niger and Aspergillus tubingensis  
RT encode ferulic acid esterases involved in degradation of complex cell  
RT wall polysaccharides";  
RT Appl. Environ. Microbiol. 63:4638-4644 (1997).  
CC -1- FUNCTION: Involved in degradation of plant cell walls. Hydrolyzes  
CC the feruloyl-arabinose ester bond in arabinoxylans, and the  
CC feruloyl-galactose ester bond in pectin.  
CC -1- CATALYTIC ACTIVITY: Feruloyl-polysaccharide + H(2)O = ferulate +  
CC polysaccharide.  
CC -1- SUBCELLULAR LOCATION: Secreted.  
CC  
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CC or send an email to [license@isb-sib.ch](mailto:license@isb-sib.ch)).  
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DR GO; GO:0030600; F:feruloyl esterase activity; ISS.  
DR GO; GO:0016998; P:cell wall catabolism; ISS.  
DR GO; GO:0045490; P:pectin catabolism; ISS.  
DR GO; GO:0045493; P:xylan catabolism; ISS.  
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DR InterPro; IPR005592; Lipase3\_N.  
DR InterPro; IPR002921; Lipase 3.

Attached seq. ~~report~~ <sup>doc</sup> #2

LOCUS Q8WZI8 521 aa linear PLN 25-OCT-2004  
 DEFINITION Feruloyl esterase B precursor (Ferulic acid esterase B) (FAEB)  
 (FAE-I) (Cinnamoyl esterase) (CinnAE).  
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 class: standard.  
 created: Feb 28, 2003.  
 sequence updated: Feb 28, 2003.  
 annotation updated: Oct 25, 2004.  
 xrefs: AJ309807.1, CAC83933.1  
 xrefs (non-sequence databases): GO0005576, GO0030600, GO0016998,  
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 PfamPF07519  
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 esterase; Signal; Xylan degradation.  
 SOURCE Aspergillus niger  
 ORGANISM Aspergillus niger  
 Eukaryota; Fungi; Ascomycota; Pezizomycotina; Eurotiomycetes;  
 Eurotiales; Trichocomaceae; mitosporic Trichocomaceae; Aspergillus.  
 REFERENCE 1 (residues 1 to 521)  
 AUTHORS de Vries, R.P., vanKuyk, P.A., Kester, H.C. and Visser, J.  
 TITLE The Aspergillus niger faeB gene encodes a second feruloyl esterase  
 involved in pectin and xylan degradation and is specifically  
 induced in the presence of aromatic compounds  
 JOURNAL Biochem. J. 363 (Pt 2), 377-386 (2002)  
 PUBMED 11931668  
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 STRAIN=CBS 120.49 / N400  
 REFERENCE 2 (residues 1 to 521)  
 AUTHORS Kroon, P.A., Faulds, C.B. and Williamson, G.  
 TITLE Purification and characterization of a novel esterase induced by  
 growth of Aspergillus niger on sugar-beet pulp  
 JOURNAL Biotechnol. Appl. Biochem. 23 (Pt 3), 255-262 (1996)  
 PUBMED 8679110  
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 REFERENCE 3 (residues 1 to 521)  
 AUTHORS Ralet, M.C., Faulds, C.B., Williamson, G. and Thibault, J.F.  
 TITLE Degradation of feruloylated oligosaccharides from sugar-beet pulp  
 and wheat bran by ferulic acid esterases from Aspergillus niger  
 JOURNAL Carbohydr. Res. 263 (2), 257-269 (1994)  
 PUBMED 7805053  
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 This SWISS-PROT entry is copyright. It is produced through a  
 collaboration between the Swiss Institute of Bioinformatics and  
 the EMBL outstation - the European Bioinformatics Institute.  
 The original entry is available from <http://www.expasy.ch/sprot>  
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 [FUNCTION] Involved in degradation of plant cell walls. Hydrolyzes  
 of the feruloyl-arabinose ester bond in arabinoxylans as well as  
 the feruloyl-galactose and feruloyl-arabinose ester bonds in  
 pectin.  
 [CATALYTIC ACTIVITY] Feruloyl-polysaccharide + H(2)O = ferulate +  
 polysaccharide.  
 [ENZYME REGULATION] Inhibited by the specific serine esterase  
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 [SUBUNIT] Homodimer (Probable).  
 [SUBCELLULAR LOCATION] Secreted.  
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